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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,538	03/11/2004	Srinka Ghosh	10030803-1	6480
<div>7590 02/28/2007 AGILENT TECHNOLOGIES, INC. Legal Department, DL429 Intellectual Property Administration P.O. Box 7599 Loveland, CO 80537-0599</div>			<div>EXAMINER CLOW, LORI A</div> <div>ART UNIT 1631 PAPER NUMBER</div>	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/28/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/798,538

Applicant(s)

GHOSH, SRINKA

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's election with traverse of Group IV, claims 19-25 in the reply filed on 20 November 2006 is acknowledged. The traversal is on the ground(s) that the methods of claim 1 and claim 12 are both directed to methods for detecting background intensity gradient and that claims 19-25 are directed to the automation of those methods. This is found persuasive and the Restriction Requirement between Groups I, II, III, and IV is hereby withdrawn. Claims 1-25 are examined herein.

Information Disclosure Statement

The Information Disclosure Statement filed 11 March 2004 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

Drawings

The drawings submitted 11 March 2004 are accepted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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Claims 1 and 12 are drawn to a method for detecting a background intensity gradient within a microarray data set comprising computing metrics, and determining a background intensity gradient comprising steps that do not include a physical transformation of matter. As emphasized by the New Interim Guidelines the claims will be evaluated for providing a practical application. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely encompass non-physical (i.e. *in-silico*) method steps which do not result in a physical transformation of matter.

Therefore, the claims must be evaluated for providing a practical application that produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case, claims 1 and 12 do not recite a tangible result such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

Claims 11, 19 and 20 are drawn to a computer program and an analysis system for detecting a background intensity gradient within a microarray data set. In the instant claims the “program stored in a computer readable medium” (claims 11 and 19) or an “analysis system” (claim 20), constitute nonfunctional descriptive material, as no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, i.e. abstract ideas, stored in a computer-readable medium, in a computer, does not make

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the claims statutory. Further, data structures, as in a “program” are descriptive material, *per se* and are not statutory because they are not capable of causing a functional change in the computer. See, e.g., Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure *per se* held nonstatutory). Computer programs are viewed as computer listings, *per se*, i.e., the description or expression of the programs, are not physical things. They are neither computer components nor statutory processes, as they are not “acts” being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and the other claimed elements of a computer that permit that computer program’s functionality to be realized.

This rejection could be overcome by amending the claims to recite that a result of the method is “displayed” or “outputted” (e.g. output to a user, a display, a memory, or another computer, etc.), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for computing a convergence metric, does not reasonably provide

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enablement for computing ANY metric, as is instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims, the instant claims are drawn to a method, system and computer program for characterizing background intensity gradients within a microarray dataset, which requires the computation of "metrics" for feature within the microarray set.

With regard to the guidance and direction, the specification provides guidance for implementing the instant method using a convergence metric χ (page 17, line 9). The convergence metric χ can be calculated according to a specific formula as presented in Figure 14. It is defined as the outer radius of the annular background region surrounding a disk-shaped feature, the semi-major or semi-minor axis length of the outer ellipse of an elliptical background region surrounding an elliptical disk-shaped feature, or half the width of a rectangular background region surrounding a rectangular shaped feature, having the greatest distance between a computed average background-pixel intensity and the median background-pixel intensity within the annular or rectangular background median (page 17, lines 10-17). Further,

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the specification provides an example of the implementation of the invention using the convergence metric χ at pages 20-34.

Therefore, it is the nature of the invention that the convergence metric χ is enabled, as one of skill in the art would not know how to implement any other metric, as the specification fails to teach how to employ any and all other metrics for the characterization of background intensity gradients within a microarray dataset. Thus, the claims are enabled for the scope presented above and not the full scope of **any** metric, as is instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,768,820, in view of Nagarajan et al. (IEEE Transactions on Nanobioscience (2002) Vol. 1, No. 2, pages 78-84).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are drawn to a method, computer program and system for detecting a background intensity gradient within a microarray dataset.

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In regard to claims 1, 12, and 20, '820 teaches background intensity computations (column 2, lines 63 and 64).

In regard to the metric computation in claims 1-3, 14, 15, 20, 22, and 23 '820 teaches the subtraction of background magnitudes (column 2, line 65) and the computation of feature positions (column 13 to column 14). The determination of single and all features is taught at column 8, lines 9-12).

In regard to the determination of a threshold, '820 teaches the threshold intensity value calculation for pixel analysis (column 12, lines 20-37).

In regard to claims 4, 7, 16, and 24, '820 teaches the calculation of mean and median pixel intensity calculations (column 13, lines 15-41).

In regard to claims 4 and 5 size calculation is taught at column 12, line 58.

In regard to claims 8, 17, 25, '820 teaches the determination of disk shaped features and circles with increasing radii from a central point (column 10, lines 15-24).

In regard to forwarding to a remote location, '820 teaches items remote from other items and communication networks to "forward" information (column 6, lines 47-60).

In regard to a computer program and system to implement the methods (claims 11, 19, and 20), '820 teaches a computer program and system at column 4, lines 65-67.

In regard to an average computed metric, as in claims 13 and 21, '820 teaches average of pixel intensity at column 13, line 30).

In regard to the area and position of features, as in claims 21, '820 teaches position calculation in a coordinate system (column 4, lines 43-48).

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'820 does not specifically teach the grouping of features, as in claims 12 and 20, however, Nagarajan et al. teach k-means clustering of partitioned microarray data (page 80, column 1). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have implemented the methods of '820 with the data clustering of Nagarajan in effort to more efficiently establish intensity gradients within microarray background data. Nagarajan motivates one to do so because the clustering approach is used for the partitioning of foreground and local background in microarray sets (page 80, columns 1 and 2).

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

February 20, 2007

Lori A. Clow, Ph.D.

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Lori A. Clow
Patent Examiner